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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/937,644	09/07/2001	Andreas Bitterhof	DFS-129-A	2087

7590 06/02/2004
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EXAMINER

MALLARI, PATRICIA C

ART UNIT	PAPER NUMBER
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3736

DATE MAILED: 06/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.		Applicant(s)	
	09/937,644		BITTERHOF, ANDREAS	
	Examiner		Art Unit	
		Patricia C. Mallari	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 February 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 September 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This is a final Office action. Any new rejections were necessitated by the applicant's amendments to the claims.

Claim Objections

Claim 15 is objected to because of the following informalities: on line 4 of the claim "the absorbent element" should be replaced with "an absorbent element".

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 3 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification fails to provide sufficient support for the insert being "formed in the shape of a disk" as claimed in claim 3. The applicant should note that adding such language into the specification of the instant application would constitute new matter. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention.

Claim Rejections - 35 USC § 102

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The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, and 6-15 are rejected under 35 U.S.C. 102(e) as being unpatentable over US Patent No. 6,126,597 to Smith et al. Smith et al. teaches an item having an absorbent element 12 capable of absorbing and retaining bodily fluid and having an analysis device 34 capable of measuring a composition of the bodily fluid (col. 4, lines 29-36; col. 5, line 65-col. 6, line 10 of Smith et al.) The analysis device 34 is disposed at an area of the hygiene item on which the bodily fluid can impinge and is separated from the absorbent element 12 by a separating means 26, 28 (figs. 2 and 3). Separating means 28 may be made of a polyethylene film (col. 5, lines 1-5), where polyethylene film is a liquid-impermeable material (see col.3, lines 51-52 of US Statutory Invention Registration No. H1298 to Ahr et al.).

As to the language “single-use” on line 1 of claim 1 and “to prevent the bodily fluid contaminated by the absorbent material from falsifying an analysis of the analysis device” on the last 2 lines of claim 1, the applicant should note that this is merely “intended use” language which cannot be relied upon to define over the prior art, since Smith et al. teaches all of the claimed elements and their recited relationships. See Ex

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parte Masham 2 USPQ 2nd 1647. Both phrases fail to denote any structure or structure element that differentiates the invention of claim 1 from that described by the prior art.

Regarding claims 2 and 6-14 the separating means 26, 28 forms an insert 10 containing the analysis device in the absorbent element 12, where an "insert" is to be understood as an area of the hygiene item separated by the separating means from the remainder of the absorbent element (p. 4, paragraph 0012 of the instant specification).

With further regard to claim 7, the insert 10 is located essentially flush-mounted with the upper side of the absorbent element 26 facing the body (figs. 2 and 3).

With further regard to claims 8-10, the analysis device 34 has a visual display unit 36 wherein a side of the separating means 26, against which the analysis device is disposed, is made transparent enough to allow a visual reading of the display unit 36 (col. 5, line 65-col. 6, line 10).

With further regard to claim 12, an adhesive 36 detachably fastens the separating means 28 containing the analysis device 26 to the absorbent element 12 (fig. 3).

With further regard to claims 13 and 14, the insert 10 may include a fluid absorbing and transport layer, made of cellulose fiber, which transfers the bodily fluid to the analysis device 36 (col. 5, lines 13-26).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Smith et al., as applied to claims 1, 2, and 6-14 above. Smith fails to describe the insert 10 as being formed in the shape of a disk. The applicant has not disclosed that having an insert of this specified shape solves any stated problem or is for any particular purpose. Moreover, it appears that the hygiene item would perform equally well with an insert of any flat shape that may fit into a piece of clothing or undergarment. Accordingly, the use of the disk shape is deemed to be a design consideration that fails to patentably distinguish over the prior art of Smith et al.

Claims 4 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Smith et al., as applied to claims 1, 2, and 6-14 above, and further in view of US Patent No. 4,114,621 to Mims, Jr. Smith fails to describe the insert having sidewalls or the edges of the insert being folded over on an upper side. Mims, Jr. teaches an insert 11, designed to be placed in an absorbent element 10, similar to that of Smith et al. The insert features sidewalls 45 extending up on a side facing the body (Col. 3, lines 37-38. figs 4 and 6 of Mims, Jr.) Figure 6 shows these sidewalls being formed by the edges of surface 34 of the insert 11 being folded over on an upper side. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to combine the sidewalls of Mims, Jr. with the item of Smith et al. in order to further reduce the chance of leakage from the insert to the absorbent element (col. 3, lines 37-38 of Mims, Jr.)

Claims 10 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Smith et al. in view of Todd et al. While Smith et al. teaches an upper layer of the

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separating means 26 allowing the color of the display unit 36 to be visualized by the wearer through the layer of the separating means 26, the reference fails to describe layer 26 as being transparent. However, Todd discloses an analysis device 10 having a display unit 24 providing a color change as an indication of analysis results, the display unit is immediately adjacent to a transparent outer layer of separating means 14 (figs. 1 and 2). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use a transparent layer as the upper side of the separating means of Smith et al., since Smith teaches an upper layer that allows visualization of the display unit through the separating means and Todd et al. describes that a transparent material would be suitable for such a visualization.

With regard to the language “that do not contain absorbent element materials” in claim 15, the applicant should note that this is merely “intended use” language that cannot be relied upon to define over Smith et al., since the reference discloses all of the claimed elements and their recited relationships. See *Ex parte Masham* 2 USPQ 2nd 1647.

Response to Arguments

Applicant's arguments with respect to claims 1-9 and 11-14 have been fully considered but they are not persuasive.

With regard to the reference Smith et al, the applicant argues that material from the absorbent element 12 contaminates the bodily fluid that flows into the analysis device 34 because the separating means in the Smith patent does not separate contaminated bodily fluid from non-contaminated bodily fluid. However, the separating

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means 28 of Smith is a liquid-impervious layer, preventing liquid transfer in either direction. Thus, the liquid impervious separating means 28 "separates [bodily fluid to be analyzed] in an essentially fluid-tight manner from the absorbent element" so that "bodily fluid that has penetrated to the absorbent element is retained by the separating means away from the analysis device" as claimed in claim 1 of the present invention.

With regard to the combination of the Smith et al. reference with the Mims, Jr. reference, the applicant contends that the goal of leakage reduction is a different goal that teaches away from the goal of the present invention as set forth in claim 1. The applicant's argument that the combination accomplishes a goal different from the applicant's goal is irrelevant since the combination of Smith et al. with Mims, Jr. teaches all of the claimed elements and their recited relationships regardless of the specified goal.

Applicant's arguments with respect to claims 10 and 15 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not

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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia C. Mallari whose telephone number is (703) 605-0422. The examiner can normally be reached on Monday-Friday 10:00 am-6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mary Beth Jones can be reached on (703) 308-3400. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


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